



Application No. 10/781,543

Amendment dated October 28, 2008

Reply to Office Action of June 11, 2008

### AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

1. (Currently amended) A composition for improving the bioavailability of a drug comprising at least one poorly bioavailable drug dissolved in an effective amount of menthol, wherein the improvement in bioavailability is determined as at least a 5% increase in the ratio of  $AUC_i/AUC_r$  above 100%;

the drug is atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, simvastatin, fenofibrate, itraconazole, bromocriptine, carbamazepine, diazepam, etoposide, camptothecin, danazole, progesterone, nitrofurantoin, estradiol, estrone, oxfendazole, proquazone, ketoprofen, nifedipine, verapamil, or glyburide;

the effective amount of menthol is about 20% to about 99% by weight of the composition; and

the composition is suitable for oral administration.

Claims 2-3

5. (Currently amended) The composition according to claim 1, wherein the drug is ~~cyclosporine~~, atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, or simvastatin, ~~or paclitaxel~~.

6. (Currently amended) The composition according to claim 1, wherein the ~~compound~~ drug is simvastatin, ~~paclitaxel~~, or cyclosporine.

7. (Withdrawn) A method for improving the bioavailability of a drug comprising dissolving the drug in an effective amount of menthol.

8. (Withdrawn) A method for improving the bioavailability of a drug comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is about 20% to about 99% by weight of the solution.

9. (Withdrawn) The method according to claim 8, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

10. (Withdrawn) The method according to claim 8, further comprising administering the composition to a mammal.

11. (Withdrawn) The method according to claim 8, wherein the amount of menthol is sufficient to increase the oral bioavailability of the drug by an amount represented by an about 10% or more increase in the average area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

12. (Withdrawn) The method according to claim 9, wherein the amount of menthol is about 60% to 99% by weight.

13. (Withdrawn) A method for reducing the variability of the bioavailability of a drug comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is sufficient to decrease the variability in the drug's bioavailability by about 10% or more of the relative standard deviation (CV%) of the area under

the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

14. (Withdrawn) The method according to claim 13, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

15. (Withdrawn) The method according to claim 13, further comprising administering the composition to a mammal.

16. (Withdrawn) The method according to claim 13, wherein the amount of menthol is sufficient to decrease the variability in the drug's bioavailability by about 50% or more of the relative standard deviation (CV%) of the area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

17. (Withdrawn) A method for increasing the extent of time that a drug provides a therapeutically significant concentration in blood or plasma comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more.

18. (Withdrawn) The method according to claim 17, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

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19. (Withdrawn) The method according to claim 17 wherein the amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more.

20. (Currently amended) The composition of claim 1, wherein the improvement in bioavailability is determined as at least a 5% increase of the average AUC as compared to the average AUC of a non-menthol containing formulation in the ratio of  $AUC_i/AUC_r$  above 100%.

21. (Withdrawn) The method of claim 8, wherein the improvement in bioavailability is determined as at least a 5% increase in the ratio of  $AUC_i/AUC_r$  above 100%.

22. (New) The composition according to claim 1, wherein the improvement in bioavailability is about 15% increase of the average AUC as compared to the average AUC of a non-menthol containing formulation.

23. (New) The composition according to claim 1, wherein the effective amount of menthol is about 60% to about 95% by weight of the composition.